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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,300	04/09/2004	Paul R. Hinton	011823-012611US	1900

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EXAMINER

CROWDER, CHUN

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/822,300

Applicant(s)

HINTON ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 13, 16 and 28-41 is/are pending in the application.
- 4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13, 16, 28 and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicant's amendments, filed 05/01/2006, have been entered.

Claims 9-12, 14, 15, and 17-27 have been canceled.

Claims 28-41 have been added.

Claims 1-4 and 13 have been amended.

Claims 1-8, 13, 16, and 28-41 are pending.

Newly added claims 29-37 have been withdrawn from consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions.

Claims 1-8, 13, 16, 28, and 38-41 are currently under consideration as they read on the elected species of an antibody daclizumab with SEQ ID NOs 118 and 122, amino acid positions 250 and 428 with substitution of glutamine and leucine.

2. The text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

This Office Action will be in response to applicant's amendment, filed 05/01/2006.

The rejections of record can be found in the previous Office Action, mailed 12/30/2005.

3. It is noted that the Restriction Requirement including Species Election is maintained for reasons of record set forth in the Office Action, mailed 12/30/2005.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

4. Claims 1-8, 13, and 38-41 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record set forth in the previous Office Action.

The instant claims are indefinite in the recitation of “daclizumab”.

Applicant’s arguments have been fully considered but have not been found convincing.

Applicant argues that the variable regions of daclizumab is disclosed in US Patent 5,530,101 and also the amino acid sequences of daclizumab are disclosed in Figure 22 of the instant specification. Further, the amino acid sequence ID NOs are recited in claim 16 and 28-37.

This is not found persuasive because the claims fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the absence of identifying characteristics such as SEQ ID NOs of amino acid sequences.

Given the disclosure of amino acid sequences of “daclizumab” in the instant specification (e.g. see Figure 22 of the instant specification), applicant is once again invited to amend the claims to recite the appropriate SEQ ID NOs of variable regions of “daclizumab”.

5. Claims 1-8, 13, 16, 28, and 38-41 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Queen et al. (US Patent 5,530,101, Reference NO:9 on IDS filed 10/29/2004) in view of Martin et al. (Molecular Cell, 2001, 7:867-877, Reference NO: 68 on IDS filed 10/29/2004) and Krueger et al. (J. Am. Acad. Dermatol. 2000, 43:448-58) for reasons of record set forth in the previous Office Action.

It is noted that SEQ ID NOs: 118 and 122 recited in claims 16 and 28 are identical to the sequences of anti-Tac antibody disclosed Queen et al. except that 250 and 428 in the Fc region in SEQ NO 122 have been substituted with glutamine and leucine, respectively.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that no *prima facie* case of obviousness has been presented, and that Martin et al. merely provide hope of modification that may yield increased FcRn binding.

This is not found persuasive for following reasons:

Contrary to applicant's argument, the teachings of reference clearly demonstrate motivation and expectation of success in making the claimed modification to a well-known antibody daclizumab.

Queen et al. teach method of making humanized therapeutic antibodies such as anti-Tac antibody (also named daclizumab, see Krueger et al.) with human IgG subclasses, specifically binds to the IL-2 receptor and the antibody can be used treating autoimmune disease, organ transplantation and any unwanted response by activated T-cells (see entire document, particularly columns 2-42).

Martin et al. teaches the mechanisms of pH-dependent binding between an FcRn and heterodimeric Fc complex using the crystal structure of rat Fc/FcRn as a model which can be used to guide rational design of the therapeutic IgGs with longer serum half-life (see entire document, particularly the Title and the Abstract).

Martin et al. teach general strategy for identification of Fc mutants with increased affinity for FcRn and that residues include 250 in the Fc region are good candidates for making mutants with increased affinity for FcRn; an approach involving random substitutions at these positions can yield further increases in binding to FcRn (e.g. see page 874, in particular). Furthermore, Martin et al. teach a mutagenesis strategy involving positions 428 with amino acid residues with hydrophobic side chains can result in stabilization of the interaction of Fc/FcRn and therefore increase Fc binding to FcRn. It is well known in the art at the time the invention was made that leucine is one of the hydrophobic amino acid residues.

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY ); and In re Burckel 201 USPQ 67 (CCPA). In re Burckel is cited in MPEP 716.02.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07.

Given the therapeutic implication of humanized antibody daclimab in treating autoimmune disease, organ transplantation and any unwanted response by activated T-cells; and the teaching of Martin et al. regarding guidance in designing of therapeutic IgGs with longer serum half-life, it would have been obvious to one of ordinary skill in the art at the time the invention was made to enhance the binding of daclimab to FcRn by substituting amino acid at positions 250 and 428 of the Fc region for prolonged serum half-lives.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 1-8, 13, 16, 28 and 38-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-12, 19-21, 25-28, 34-43, and 49 of copending USSN: 10/687,118, claims 1-4, 14, and 15 of copending USSN: 11/102, 621, and claims 1-8, 13, 15, and 16 of the copending USSN: 10/966,673.

These rejections are maintained until a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) is timely filed.

7. Upon further consideration as well as applicant's amendments, the previous rejection under **35 U.S.C. 112, second paragraph regarding the use of Trademark and 35 U.S.C. 102(b)** have been withdrawn.

8. ***Conclusion: no claim is allowed.***


9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.  
Patent Examiner  
June 28, 2006

  
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PRIMARY EXAMINER  
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7/3/06